

land use, and impacts resulting from increased use and changes in use patterns for chemical substances.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action), particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alternatives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

§25.31e Environmental assessment for destruction of condemned, enjoined, detained, or recalled articles—Format 5.

For actions to destroy or dispose of articles condemned after seizure, detention, or FDA-initiated recall, or after distribution or use of the article has been enjoined, the person proposing the action shall, at the request of the agency, prepare an environmental assessment in the following format when the method of destruction or disposition results in release of toxic substances:

ENVIRONMENTAL ASSESSMENT

1. *Purpose of and need for action:* Briefly describe the underlying purpose and need for the article to be destroyed, the proposed method of destruction or disposal, the locations where the proposed destruction or other disposal will occur, and the types of environments present at and adjacent to those locations.

2. *Description of potentially toxic substances present in the article:* Provide complete nomenclature, CAS Registry numbers (if available), molecular weight, structural formulae, physical description, and concentration of the potentially toxic substances in the article.

3. *Introduction of potentially toxic substances into the environment:* For transport of the ar-

ticle to the site(s) of disposition, cite and certify compliance with any applicable Federal, State, and local emissions requirements. List to the extent possible the potentially toxic substances expected to enter the environment at the site(s) of destruction and/or disposal of the article. Describe the approximate concentrations of emissions; state the controls exercised; and include a citation of, and statement of compliance with, applicable requirements at the Federal, State, and local level.

4. *Fate of potentially toxic emitted substances in the environment:* Report physical/chemical and other data in the scientific literature relating to the fate of potentially toxic substances expected to be emitted into the environment as a result of destruction or other disposal of the article. Such physical/chemical parameters include water solubility, solubility in organic solvents, *n*-octanol/water partition coefficient, dissociation constants, vapor pressure, ultraviolet-visible absorption spectrum, ability to form chemical complexes, storage stability, etc.

5. *Environmental effects of potentially toxic substances expected to be emitted into the environment.* Report information on the effects of the emitted substances on animals, plants, humans, other organisms, and effects at the ecosystem level. Compare the expected environmental concentrations of the substances with the concentrations that cause adverse effects.

6. *Description of alternative methods of destruction and/or disposal and the expected environmental consequences:* Describe the environmental impact of reasonable alternatives (including no action) particularly those that will enhance the quality of the environment and that will avoid some or all of the adverse environmental effects of the proposed method of destruction or other disposition.

7. *Comparative analysis of proposed methods of destruction or other disposition and alternative methods:* Provide a comparative analysis of the environmental benefits and risks of the proposed and alternative methods. Identify the preferred action based on environmental factors.

8. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

9. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

(Approved by the Office of Management and Budget under control number 0910-0190)

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